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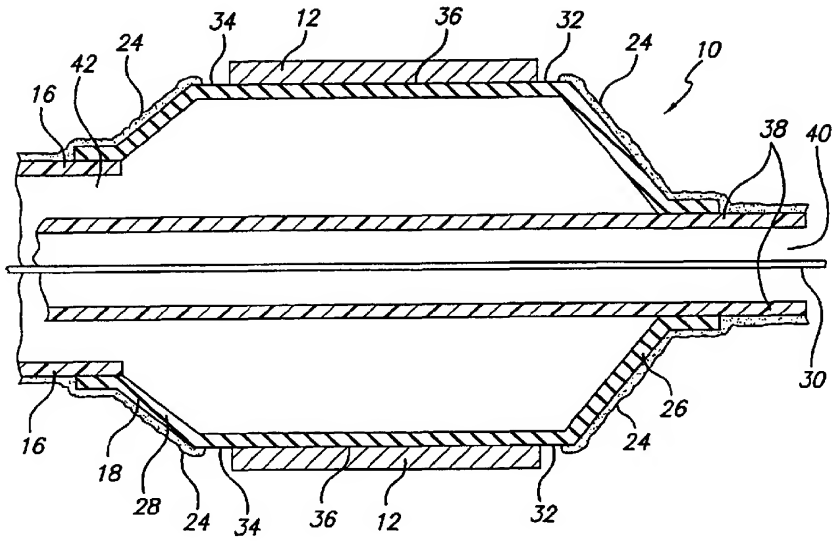
(54) Title: SELECTIVELY COATED STENT DELIVERY SYSTEM AND METHOD OF MANUFACTURE THEREOF



(57) Abstract: The invention is directed to a stent delivery system having a coating selectively applied thereto. The stent delivery system has an expandable device with a stent. The coating may coat all portions of the expandable device except those areas under the stent. The coating may selectively coat areas under the stent in order to aid in stent deliverability and/or deployment. The coating may partially cover the stent in order to aid stent deliverability and stent fixation on the catheter. The coating may be a lubricious material, such as a hydrophilic material. The coating may be applied through various techniques, including the use of templates such as elastic bands that shield selected areas of the catheter.

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SELECTIVELY COATED STENT DELIVERY SYSTEM AND METHOD OF MANUFACTURE THEREOF

BACKGROUND OF THE INVENTION

This invention relates to devices for the treatment of heart disease and particularly to endo-arterial prostheses, including stents and stent delivery systems. More particularly, the invention relates to a selectively coated stent delivery system.

Several interventional treatment modalities are presently used for heart disease, including balloon and laser angioplasty, atherectomy, and by-pass surgery. In typical coronary balloon angioplasty procedures, a guiding catheter having a distal tip is percutaneously introduced through the femoral artery into the cardiovascular system of a patient using a conventional Seldinger technique and advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium of a coronary artery. A guidewire is positioned within an inner lumen of a dilatation catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon on the distal portion thereof is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once in position across the lesion, the balloon is inflated to compress the plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon is then deflated so that blood flow can be resumed through the dilated artery and the dilatation catheter can be removed therefrom. Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures can be found in U.S. Pat. No. 4,323,071 (Simpson-Robert); U.S. Pat. No. 4,439,185 (Lindquist); U.S. Pat. No. 4,516,972 (Samson); U.S. Pat. No. 4,538,622 (Samson, et al.); U.S. Pat. No. 4,554,929 (Samson, et al.); U.S. Pat. No. 4,616,652 (Simpson); U.S. Pat. No. 4,638,805 (Powell); U.S. Pat. No. 4,748,982 (Horzewski, et al.); U.S. Pat. No. 5,507,768 (Lau, et al.); U.S. Pat. No. 5,451,233 (Yock); and U.S. Pat. No. 5,458,651 (Klemm, et al.), which are hereby incorporated herein in their entirety by reference thereto.

One problem that can occur during balloon angioplasty procedures is the formation of intimal flaps which can collapse and occlude the artery when the balloon is deflated at the end

of the angioplasty procedure. Another problem characteristic of balloon angioplasty procedures is the large number of patients who are subject to restenosis in the treated artery. In the case of restenosis, the treated artery may again be subjected to balloon angioplasty or to other treatments such as by-pass surgery, if additional balloon angioplasty procedures are not warranted. However, in the event of a partial or total occlusion of a coronary artery by the collapse of a dissected arterial lining after the balloon is deflated, the patient may require immediate medical attention, particularly in the coronary arteries.

A focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically shaped intravascular devices which are placed within an artery to hold it open. The device can be used to reduce the likelihood of restenosis and to maintain the patency of a blood vessel immediately after intravascular treatments. In some circumstances, they can also be used as the primary treatment device where they are expanded to dilate a stenosis and then left in place. Further details of stents can be found in U.S. Patent 3,868,956 (Alfidi et al.); U.S. Patent 4,512,338 (Balko et al.); U.S. Patent 4,553,545 (Maass et al.); U.S. Patent 4,733,665 (Palmaz); U.S. Patent 4,762,128 (Rosenbluth); U.S. Patent 4,800,882 (Gianturco); U.S. Patent 4,856,516 (Hillstead); U.S. Patent 4,886,062 (Wiktor); U.S. Patent 5,421,955 (Lau); and U.S. Patent 5,569,295 (Lam), which are hereby incorporated herein in their entirety by reference thereto.

One method and system developed for delivering stents to desired locations within the patient's body lumen involves crimping a stent about an expandable member, such as a balloon on the distal end of a catheter, advancing the catheter through the patient's vascular system until the stent is in the desired location within a blood vessel, and then inflating the expandable member on the catheter to expand the stent within the blood vessel. The expandable member is then deflated and the catheter withdrawn, leaving the expanded stent within the blood vessel, holding open the passageway thereof.

Advancing a catheter through a patient's vasculature, which can involve traversing sharp bends and other obstacles, can be facilitated by the use of a lubricious coating on the catheter. For example, silicon-based lubricants are known in the art for use as catheter coatings. Hydrophilic materials, which become increasingly lubricious in the presence of water, can also be used to coat the catheter. These and other lubricious coatings can provide lubrication that decreases friction between the catheter and patient's vasculature. Traditionally, it has been preferable to fully coat the distal portion of the catheter, such as a

balloon dilatation catheter, including the distal shaft, balloon, and tip. Fully coating the portion of the catheter that enters the patient's anatomy can enhance system deliverability, including the ability to cross lesions.

Such coatings have generally not been used with stent delivery systems, possibly due to questions as to potential interactions between the stent and the lubricious coating. Coating underneath the stent may not appreciably contribute to improving the deliverability of the device. Moreover, when a stent is mounted on a catheter in such a way that the stent overlies a highly lubricious coating, the highly lubricious coating might increase the risk of the stent sliding off of the catheter. Depending on the particular device and coating, a stent-underlying coating might interfere with stent deployment, or become dislodged during stent deployment.

What has been needed and heretofore unavailable is an improved means for improving the ease with which a stent delivery system, such as a balloon catheter, can be advanced through a patient's vasculature. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The invention is directed to a catheter having a selective coating. In particular, the coating is selectively positioned on the catheter, so that some areas of the catheter are coated and others are uncoated.

In one embodiment of the invention, the coating is a lubricious material that facilitates introduction of the catheter into portions of a human anatomy. In a further embodiment, the coating is a hydrophilic material.

In one embodiment of the invention, catheter is part of a stent delivery system, with an expandable device and a stent positioned on the expandable device. The expandable device may be a balloon. The lubricious coating is selectively positioned to coat the balloon, except for those areas immediately adjacent to and underlying the stent.

In a further embodiment of the invention, the lubricious coating extends to the edge of the stent. The lubricious coating may even extend over the distal and/or proximal edge of the stent, or may extend at least partially underneath the stent.

The selective coating can be applied by hand to achieve the desired configuration. In a further embodiment of the invention, the selective coating is applied by a device having a sensor and controller that applies the coating only where desired. The selctive coating may be applied by spraying, dipping, sputtering, or other application methods.

A template may be used to control the application of the coating by shielding selected areas from application of the coating. For example, an elastic band can be placed around selected portions of the balloon catheter, so that the coating can be applied to other areas of the balloon catheter without contacting the areas covered by the elastic band.

For coatings which rely on a pre-treatment and/or a post-treatment process to adhere the coating to the balloon, the selective coating can be achieved by locally omitting necessary pre-treatment and/or post-treatment processes. A template can be used to control application of the pre-treatment and/or post-treatment process.

While several of the specific examples cited herein discuss the invention being used for stent delivery in a patient's vasculature, the invention has application in other areas of a patient's anatomy where a stent or other device is delivered through or to a body lumen. The invention could be used in delivery systems used in coronary, peripheral, renal, neurovascular, venous, biliary, digestive, urinary, and/or other applications in body lumens. It is compatible with various catheter configurations, including over-the-wire, rapid exchange, fixed-wire, and other configurations, and with numerous catheter and balloon materials.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side view, in partial cross-section, of a stent delivery system, embodying features of an embodiment of the invention, introducing a stent into an artery.

FIG. 1a is a side view, in cross-section, of the stent delivery system of FIG. 1.

FIG. 2 is a side view, in partial cross-section, of the stent delivery system of FIG. 1 deploying a stent in an artery.

FIG. 3 is a side view, in cross-section, of the artery depicted in FIGS. 1 and 2 after the stent delivery system is withdrawn, with the stent implanted in the artery.

FIG. 4 is a side view, in cross-section, of a stent delivery system embodying features of a further embodiment of the invention.

FIG. 5 is a side view, in cross-section, of a stent delivery system embodying features of a further embodiment of the invention.

FIG. 6 is a side view, in cross-section, of a stent delivery system embodying features

of a further embodiment of the invention.

FIG. 7 is a side view, in cross-section, of a stent delivery system embodying features of a further embodiment of the invention.

FIG. 8 is a side view, in cross-section, of a stent delivery system embodying features of a further embodiment of the invention.

FIG. 9 is a side view, in cross-section, of a stent delivery system embodying features of a further embodiment of the invention.

FIGS. 10a, 10b, 10c, and 10d depict in side view a stent delivery system being manufactured in accordance with an embodiment of the invention.

FIGS. 11a, 11b, and 11c depict in side view a stent delivery system being manufactured in accordance with an embodiment of the invention.

FIGS. 12a, 12b, 12c, 12d, and 12e depict in side view a stent delivery system being manufactured in accordance with an embodiment of the invention.

FIGS. 13a, 13b, 13c, and 13d depict in side view a stent delivery system being manufactured in accordance with an embodiment of the invention.

FIGS. 14a and 14b depict in side view a stent delivery system being manufactured in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is depicted in FIGS. 1-14b for use in various body lumens and procedures, including use in dilated arteries during balloon angioplasties. However, the present invention is not limited to use in blood vessels or angioplasties, but can be used in other body lumens and procedures, including treatment of urinary, digestive, or bile ducts.

A stent delivery system is generally used to deliver a stent intraluminally, as is known in the art. The stent is used primarily to ensure the patency of the body lumen in which it is implanted. For example, the stent may be implanted in the coronary arteries after an angioplasty procedure to reinforce the artery against recoil or to tack up a dissection in the arterial wall. The stent is useful for implanting in other body lumens, such as the carotid arteries, illiacs, cerebral vasculature, and other peripheral veins and arteries.

FIGS. 1 and 1a illustrate a stent delivery system 10 incorporating features of the invention, with FIG. 1a depicting a close-up view of the balloon portion of the stent delivery system. The stent delivery system 10 includes a stent 12 mounted on a delivery catheter 14.

The delivery catheter 14 has a shaft 16 and an expandable device, which is depicted as an expandable balloon 18, for expanding the stent 12 within coronary artery 20. The artery 20, as shown in FIG. 1, has a dissected lining 22 which has occluded a portion of the arterial passageway.

In the embodiment of FIG. 1, the delivery catheter 14 onto which the stent 12 is mounted is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 18 may be formed of suitable materials, including polyethylene, polyethylene terephthalate, polyurethane, polyvinyl chloride, nylon and other polyamides, and ionomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other materials may also be used, depending on the particular application.

A coating 24 is positioned on selective portions of the delivery catheter 14, including selective portions of the balloon 18. In the particular embodiment depicted, the coating 24 is applied to essentially all exposed surfaces of the shaft 16 and balloon 18, including the balloon portion 26 distal of the stent 12 and the balloon portion 28 proximal of the stent 12. The coating 24 is not present, however, in those areas 32, 34 immediately adjacent to the stent or the central area 36 underlying the stent 12. Such areas remain uncoated, i.e., are free of the coating 24. The coating 24 may be a lubricious coating, which can facilitate advancement of the stent delivery system 10 through the vasculature, including the artery 20.

The coating 24 can comprise many different materials, depending on the particular application. The coating 24 may be a lubricious material, such as a silicon-based lubricant. Other lubricious materials could also be used, including hydrophilic materials, which become increasingly lubricious in the presence of water. Other coatings could also be used in accordance with the invention. For example, a coating of a selected drug or of a drug-delivery material could be selectively applied to portions of the stent delivery system. Such an embodiment might include a localized drug applied to selected portions of the balloon catheter so that the drug is applied to the arterial wall as the balloon is expanded against the arterial wall during stent deployment. Examples of materials suitable for use with the invention are described in pending patent application Serial No. 09/016,694, filed Jan. 30, 1998, entitled "Lubricious Hydrophilic Coating For An Intracorporeal Medical Device," and in pending patent application Serial No. 09/240,914, filed January 29, 1999, entitled "Therapeutic, Diagnostic, Or Hydrophilic Coating For An Intracorporeal Medical Device," the contents of which are incorporated herein by reference, respectively.

In order for the stent 12 to remain in place on the balloon 18 during delivery to the site of the damage within the artery 20, the stent 12 is compressed onto the balloon. Other means for securing the stent 12 onto the balloon 18 may also be used, such as providing a covering sheath over the stent, or providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon. Thermal and/or pressure processes can also be used to secure the stent to the balloon. The stent 12 may be secured to the balloon 18 before, during, or after application of the coating 24, depending on the particular application.

Turning to FIG. 1a, the balloon catheter 14 of the particular embodiment includes an inner shaft 38 that defines an inner lumen 40 through which the guide wire 30 can pass. The balloon catheter 14 also includes an inflation passage 42, which in this embodiment is a passage defined between the main catheter shaft 16 and the inner shaft 38. The inflation passage 42 provides a path through which an inflation material, such as air or water, can be introduced to inflate the balloon 18.

The delivery of the stent 12 is accomplished in the following manner. The stent 12 is first mounted onto the inflatable balloon 18 on the distal extremity of the delivery catheter 14. The balloon 18 may be slightly inflated to secure the stent 12 onto the exterior of the balloon 18. The stent delivery system 10, including the catheter-stent assembly, is introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guidewire 30 is disposed across a stenosed area or the damaged arterial section having a detached or dissected lining 22, and then the stent delivery system 10 is advanced over the guidewire 30 within the artery 20 until the stent 12 (and balloon 18) is directly under the detached lining 22. The balloon 18 is expanded, expanding the stent 12 against the artery 20, which is illustrated in FIG. 2. While not shown in the drawing, the artery 20 may be expanded slightly by the expansion of the stent 12 to seat or otherwise fix the stent 12 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded in order to facilitate passage of blood or other fluid therethrough.

After the stent 12 has been deployed, the balloon 18 is deflated and the catheter 14 withdrawn from the artery 20, leaving the stent 12 in position to hold open the artery 20, as illustrated by FIG. 3. The stent 12, which typically presses against the wall of the artery 20, will eventually be covered with endothelial cell growth which further minimizes blood flow interference.

Note that many stents do not present a solid surface, but instead comprise an open structure with multiple openings, such as the openings 44 in the stent depicted in FIG. 1. Although FIG. 1 depicts the areas of the balloon underlying these openings as uncoated, such openings can be either coated or left uncoated, depending on the particular application, without departing from the scope of the invention.

FIG. 4 depicts a further embodiment of the invention, wherein the lubricious coating 24 covers all exterior portions of the balloon 18 except for the area 36 that the stent 12 overlies. The coating 24 even covers areas 32, 34 immediately adjacent to the stent 12, so that there is no appreciable gap between the stent 12 and the lubricious coating 24.

FIG. 5 depicts another embodiment of the invention, wherein the coating 24 extends to and partially under the stent 12. In the particular embodiment shown, the coating 24 covers only a small portion of the area 36 underneath the stent 12, thereby reducing the chances for any impact on stent retention and deployment that might occur if the coating 24 covered the entire area 36 of the balloon 18 under the stent 12.

FIG. 6 depicts a further embodiment of the invention, wherein the coating 24 extends to and partially over the distal end 46 and proximal end 48 of the stent 12. The coating 24 in such an embodiment can facilitate deliverability of the stent delivery system 10 by reducing the potential friction at the ends 46, 48 of the stent 12. Such an embodiment could be manufactured by applying the coating 12 after the stent 12 is already secured to the balloon 18. Such an application could also assist in retaining the stent 12 onto the balloon 18, depending on the coating and other features of a particular stent delivery system. Note that the coating 24 could be applied to cover just the distal end 46, or just the proximal end 48, depending on the particular application.

Turning to FIG. 7, a further embodiment of the invention has banded coated portions 50 that encircle the balloon 18 underneath the stent 12. Depending on the particular application, such coated bands 50, combined with alternating uncoated bands 52 of the balloon surface, could assist in stent deployment. For example, the coated bands 50 may permit overlying portions of stent 12 to "slide" during deployment, while portions of the stent overlying the uncoated portions 52 are firmly held in place. The selected application of coating could also assist in deliverability, where selected portions of the stent 12 that overlie the coated portions 50 can "slide" on the balloon 18 as the stent delivery system 10 winds through a tortuous anatomy. Although the embodiment of FIG. 7 depicts alternating bands

of coating, other patterns are within the scope of the invention, such as longitudinal strips, spirals, or other patterns. Moreover, such patterns of coated and uncoated areas could be applied to areas that do not underlie the stent, such as the distal area 26 and proximal area 28 of the balloon.

FIG. 8 depicts a stent delivery system 10 wherein the coating 24 is applied only to the balloon 18, but not to other portions of the catheter 14, such as the catheter shaft 16. In the embodiment depicted in FIG. 9, a coating 24 of a first material is applied to the balloon 18, while the catheter shaft 16 has a coating 54 of a second material. Such an application may be desirable where the balloon 18 and portions of the catheter 14, such as the catheter shaft 16, are made of materials that interact differently with different coatings. For example, where a first coating 24 is particularly useful with the balloon material but is less suited for use on the rest of the catheter, the first coating 24 can be selectively applied to the balloon. The rest of the catheter can be covered with a second coating 54 more suited to the material of the rest of the catheter.

Turning to FIGS. 10a-10c, a method for selectively applying the coating to a delivery catheter is depicted. FIG. 10a depicts the balloon catheter 14. The balloon catheter 14 is typically cleaned, which may involve sterilization, prior to application of the coating. Techniques for such cleaning, including ultrasonic cleaning, are well known in the art. The balloon catheter 14 may include guide markings 56 that help to guide application of the coating and/or mounting of the stent onto the balloon 18. In the embodiment shown, the guide markings 56 are on the surface of the balloon 18. Alternatively, the guide markings could be positioned on a surface that is actually covered by the balloon, such as the outer surface of the inner shaft 38 depicted in FIG. 1a. Such markings could be visible through the balloon material, especially where the balloon material is substantially transparent.

FIG.10b depicts the coating 24 being selectively applied by a coating-dispensing device, which is depicted as a selectively activated sprayer 58, similar to that used in ink-jet printers. Other dispensing devices are also within the scope of the invention, including sponges, brushes, or other dispensing devices. Movement of the balloon catheter 14 and sprayer 58 may be coordinated to selectively coat areas of the balloon catheter surface. In the particular embodiment of FIG. 10b, the sprayer 58 is configured to move along a track 60 running lengthwise along the balloon catheter 14, while the balloon catheter 14 is rotated about its longitudinal axis 62, thus permitting the sprayer 58 to be positioned over many

surface areas of the balloon catheter 14. Alternatively, the sprayer could be entirely stationary, with the balloon catheter performing all movements necessary to present selected surface areas to the sprayer for coating. In another embodiment, the balloon catheter can be stationary, with the sprayer performing all movements necessary to position the sprayer over surface areas of the balloon catheter for coating. The application system may include a detector and control system (not shown) that detects when the sprayer is between the markings, and shuts off the sprayer at such times to prevent application of the coating between the markings.

FIG. 10c depicts another embodiment of the invention, wherein multiple coating-dispensing units, depicted as an array 64 of sprayers 58, are used to apply the coating. By selectively activating and/or positioning the sprayers 58 in the array 64, only minimal movement of the balloon catheter 14 and/or sprayer array 64 can achieve selective coating of the desired areas of the balloon catheter 14. The sprayer array 64 may be large enough, such as where it forms a cylindrical array (not shown) that surrounds the desired portions of the balloon catheter, so that no movement of the balloon catheter or sprayer array is necessary to achieve the desired selective coating of the balloon catheter. In such an embodiment, the selective activation and/or positioning of the sprayers in the array could be sufficient to coat the selected areas of the balloon catheter.

During coating process, the balloon may be partially or fully inflated to prevent bare (uncoated) areas that might be caused by folds in a deflated balloon. Alternatively, the balloon could intentionally be left uninflated and/or unfolded, with the uninflated folds positioned so as to cover areas of balloon that are desired to be left uncoated.

FIG. 10d depicts the finished stent delivery system 10, with the coating 24 selectively applied and with the stent 12 mounted on the balloon 18. Note that the stent 12 can be mounted on the balloon 18 before, during, or after the application of the coating 24, depending on the particular application, without departing from the invention. Additionally, the guide markings 56 for guiding the coating process can also be used to guide stent placement.

FIGS. 11a through 11d depict another method for manufacturing a stent delivery system in accordance with an embodiment of the invention. In FIG. 11a, an elastic band 66 is positioned on the balloon 18 as a template that locally shields selective areas of the balloon 18 that are desired to be left uncoated. The balloon 18 may be partially expanded after the band 66 is positioned thereon on in order to make sure that the band 66 fits tightly on the balloon 18, thereby preventing any coating from inadvertently passing under the band 66 and

coating the areas of the balloon 18 thereunder. Guide markings (not shown) may be used to guide placement of the band, as well as to guide placement of the stent. Note that other template-like devices could be used, and not just elastic bands, depending on the particular application.

FIG. 11b depicts the coating being applied to the balloon. In the particular embodiment of FIG. 11b, the coating material is applied by spraying the entire balloon catheter 14 with the coating material 24, with the elastic band 66 preventing the coating material 24 from contacting the covered portions of the balloon 18. Various other coating application methods could be used, such as dipping the balloon catheter directly into the coating material, or sputter-coating or directly brushing the coating material onto the balloon catheter.

In FIG. 11c, the elastic band 66 is shown removed from balloon 18, with the stent 12 secured to the balloon 18. Note that the stent can be secured to the balloon before or as the band is secured to the balloon catheter, or the stent can be secured to the balloon after the band is removed, depending on the application.

Another method for selectively coating the balloon catheter involves the selective pre-treatment of the balloon catheter , wherein the coating will only adhere to portions of the balloon catheter that have been subjected to the pre-treatment. In FIG. 12a, the balloon catheter 14 is depicted with a template, depicted as an elastic band 66, mounted on the balloon 18. With the elastic band 66 in place, a pre-treatment is applied to the balloon. For example, the pre-treatment could be a plasma treatment that will impact the exposed areas of the balloon catheter, but that will not penetrate the elastic band 66 to reach the underlying areas of the balloon catheter 14. Other pre-treatments could include the application of a pre-treatment coating that helps to secure the main coating onto the balloon catheter. The elastic band 66 or other template serves to shield the underlying areas of the balloon 18 from being pre-treated. FIG. 12b depicts the band 66 removed from the balloon 18, with all areas thereof now pre-treated except the balloon surface area 68 that had been covered by the elastic band 66. In FIG. 12c, the coating 24 is applied to the balloon catheter 14. In FIG. 12d, the excess and/or loose coating 24 is removed from the balloon catheter 14. In the embodiment of FIG. 12d, the excess and/or loose coating is removed by running the balloon catheter 14 lengthwise through a pair of sponge "wipers" 70 that are run lengthwise down the balloon catheter 14. Because the coating only adheres to the areas of the balloon catheter 14 that have been

subjected to the pre-treatment, and not to the area 68 that was shielded by the elastic band 66 during pre-treatment, the finished stent delivery system 10, depicted in FIG. 12e with the stent mounted thereon, has the coating 24 selectively applied only to the desired areas.

Note that the stent can be secured to the balloon before or as the band is secured to the balloon catheter, or the stent can be secured to the balloon after the band is removed, depending on the application. Moreover, depending on the particular material(s) of the balloon and catheter, the pre-treatment may cause the coating to adhere only to areas that are formed from a receptive material. For example, the catheter shaft may be formed from a material that is not receptive to the pre-treatment and/or coating material, so that the coating material will only adhere to the balloon material, and not to the catheter shaft material, even where both the balloon and catheter shaft have been exposed to the same pre-treatment.

FIGS. 13a-13f depict in side view a stent delivery system being manufactured in accordance with a further embodiment of the invention that uses a post-treatment to adhere the coating to the balloon catheter 14. In FIG. 13a, the coating 24 is applied to the balloon catheter 14. In FIG. 13b, a template in the form of an elastic band 66 is positioned on the balloon 18 to shield portions thereof from the post-treatment. With the elastic band 66 in place, post-treatment is applied to the balloon catheter 14. In the particular embodiment shown, the post-treatment is provided by an ultraviolet light source 72, with the ultraviolet light curing the coating 24 onto the balloon catheter 14. Exposed areas of the coating 24 are cured onto the balloon catheter 14, while the area underlying the elastic band 66 is shielded and left uncured. While the use of ultra-violet light is depicted, the post-treatment may be achieved by various methods, depending on various design choices, including the coatings and balloon catheter materials involved. Other post-treatments may include the application of a secondary coating that secures the primary coating to the balloon catheter, or the use of heat or other treatments to cure or otherwise secure the coating to the balloon catheter. After the elastic band 66 is removed, the coating 24 covers all portions of the balloon catheter 14. FIG. 13c depicts removal of the excess and/or loose coating 24, which in the embodiment depicted is achieved through the use of a pair of sponge "wipers" 70 that are run lengthwise along the balloon catheter 14. The coating 24 will wipe off of those areas of the balloon catheter 14 that were protected by the elastic band 66 during the post-treatment, but the coating 24 will adhere to those areas exposed to the post-treatment. The finished stent delivery system 10, depicted in FIG. 13f, shows the stent 12 secure onto the balloon 18 with the coating 24 on selected

areas of the balloon catheter 14. Note that the stent can be secured to the balloon before or as the band is secured to the balloon catheter, or the stent can be secured to the balloon after the band is removed, depending on the application.

FIGS. 14a through 14b depict a further embodiment of the invention, wherein the coating is applied to the large areas of the balloon catheter and then selectively removed. FIG. 14a depicts the balloon catheter 14 with the coating 24 applied thereto. In FIG. 14b, selected areas of the coating 24 are treated with a laser 74, which targets a laser beam 76 that vaporizes the coating 24 without harming the underlying areas of the balloon catheter 14. Alternatively, the laser 74 may degrade the coating's ability to adhere to the balloon catheter, thereby making the lazed areas of coating easy to remove by the techniques discussed previously for removing loose and/or excess coatings, such as the sponge wipers depicted in FIG. 12e. Other methods for removing the coating, which can be used in addition to or in lieu of the laser treatment, include selective application of solvents or the use of a tool to mechanically remove the coating from desired areas.

Various combinations of the above-identified manufacturing methods can be used, depending on the particular application. For example, some coating materials may require both a pre-treatment of the balloon surface and a post-treatment of the coating to ensure their adhesion to the balloon. A specific example is where a polyethylene-oxide hydrophilic coating is used, the balloon may need to be plasma treated prior to application of the coating, as depicted in FIG. 12b, and the coating may subsequently need to be treated with an ultraviolet light to cure the coating, as depicted in FIG. 13c. A template may be used to selectively control application of the coating, of the pre-treatment, of the post-treatment, or any combination thereof.

Although preferred and alternative embodiments of the invention have been described and illustrated, the invention is susceptible to modifications and adaptations within the ability of those skilled in the art and without the exercise of inventive faculty. Thus, it should be understood that various changes in form, detail, and usage of the present invention may be made without departing from the spirit and scope of the invention. For example, while the present invention has been described herein in terms of devices for use within a patient's blood vessel, the invention can also be employed for devices for use within other body lumens. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A stent delivery system, comprising:

a catheter shaft;

an expandable device positioned on the catheter shaft;

a coating on the expandable device, wherein the coating coats at least a portion of the surface area of the expandable device, but at least a portion of the surface area of the expandable device is uncoated by the coating; and

a stent mounted onto the expandable device, wherein the stent is positioned so as to overlay at least a portion of the uncoated portion of the expandable device.

2. The stent delivery system of claim 1, wherein the stent covers a portion of the surface area of the expandable device, and the stent-covered portion of the surface area is uncoated by the coating.

3. The stent delivery system of claim 1, wherein the expandable device has surface areas distal of the stent, and at least a portion of the distal area is uncoated.

4. The stent delivery system of claim 1, wherein the expandable device has surface areas proximal of the stent, and at least a portion of the proximal area is uncoated.

5. The stent delivery system of claim 1, wherein the stent has a surface area, and at least a portion of the stent surface area is coated by the coating.

6. The stent delivery system of claim 1, wherein the stent overlies at least a portion of the coated portion of the expandable device.

7. The stent delivery system of claim 1, wherein the expandable device is a balloon.

8. The stent delivery system of claim 1, wherein the coating is a lubricious material.

9. The stent delivery system of claim 8, wherein the coating is a hydrophilic material.

10. A catheter, the catheter comprising:

a catheter shaft;

an expandable device; and

a primary coating on the expandable device, wherein the primary coating coats at least a portion of the surface area of the expandable device, but at least a portion of the surface area

of the expandable device is free of the primary coating.

11. The catheter of claim 10, wherein the expandable device has a distal portion, and the primary coating covers at least a portion of the distal portion.

12. The catheter of claim 10, wherein the expandable device has a proximal portion, and the primary coating covers at least a portion of the proximal portion.

13. The catheter of claim 10, wherein the expandable device has a central portion, and the central portion is free of the primary coating.

14. The catheter of claim 10, wherein the expandable device is a balloon.

15. The catheter of claim 10, wherein the primary coating coats at least a portion of the surface of the shaft.

16. The catheter of claim 10, wherein the shaft is free of the primary coating, and at least a portion of the shaft is coated by a secondary coating.

17. The catheter of claim 16, wherein the expandable device is free of the secondary coating.

18. A method for manufacturing a catheter, the method comprising the steps of:

providing a catheter with an expandable device;

applying a coating to one or more portions of the catheter, but leaving one or more portions of the catheter free of the coating.

19. The method of claim 18, wherein the step of coating the catheters comprises the steps of:

placing a template over one or more selected portions of the catheter;

applying the coating to the catheter, wherein the template shields the selected portions of the catheter from application of the coating; and

removing the template from the catheter.

20. The method of claim 19, wherein the step of placing the template includes placing the template over one or more selected portions of the expandable device.

21. The method of claim 20, wherein the expandable device comprises a balloon, and the template comprises an elastic band.

22. The method of claim 21, including the further step of:

partially expanding the balloon.

23. A method of manufacturing a catheter, the method comprising the steps of:

providing a catheter with an expandable device;

treating one or more portions of the catheter, but leaving one or more portions of the catheter untreated; and

applying a coating to one or more portions of the catheter.

24. The method of claim 23, wherein the step of treating one or more portions of the catheter is performed prior to the step of applying the coating.

25. The method of claim 23, wherein the step of treating one or more portions of the catheter is performed after the step of applying the coating.

26. The method of claim 23, wherein the step of treating one or more portions of the catheter includes the further steps of:

placing a template over one or more selected portions of the catheter;

applying treatment to the catheter, wherein the template shields the selected portions of the catheter from the treatment; and

removing the template from the catheter.

27. A method of manufacturing a catheter, comprising the steps of:

providing a catheter;

applying a coating to one or more portions of the catheter; and

removing the coating from one or more portions of the catheter, but leaving the coating on one or more coated portions of the catheter.

28. The method of claim 27, wherein the step of removing the coating includes the step of:

applying a laser beam to the coating.

29. The method of claim 27, wherein the coating comprises a lubricious coating.

30. A stent delivery system, comprising:

a catheter shaft;

an expandable device positioned on the catheter shaft;

a stent mounted onto the expandable device, wherein the stent is positioned so as to overlay at least a portion of the uncoated portion of the expandable device; and

a coating, wherein the coating coats at least a portion of the surface area of the expandable device, but at least a portion of the surface area of the expandable device is free of the coating, and the coating coats at least a portion of the stent, but at least a portion of the stent is free of the coating.

31. The stent delivery system of claim 30, wherein the stent has a distal end, and the coating covers the stent distal end.

32. The stent delivery system of claim 31, wherein the stent has a proximal end, and the coating covers the stent proximal end.

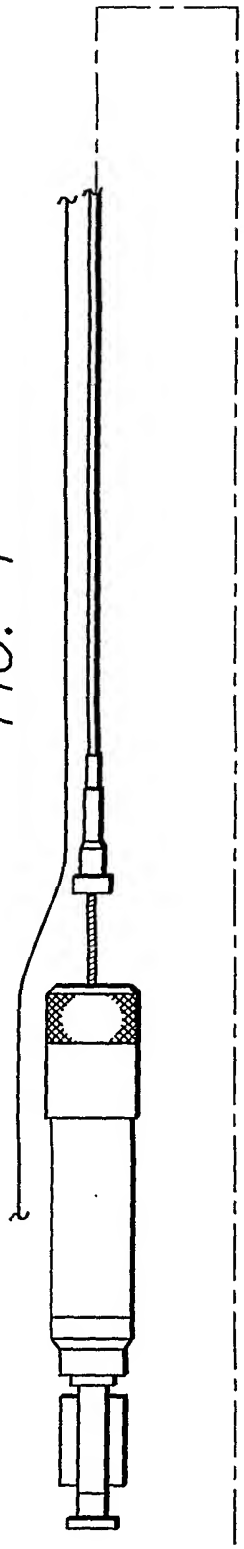

FIG. 1

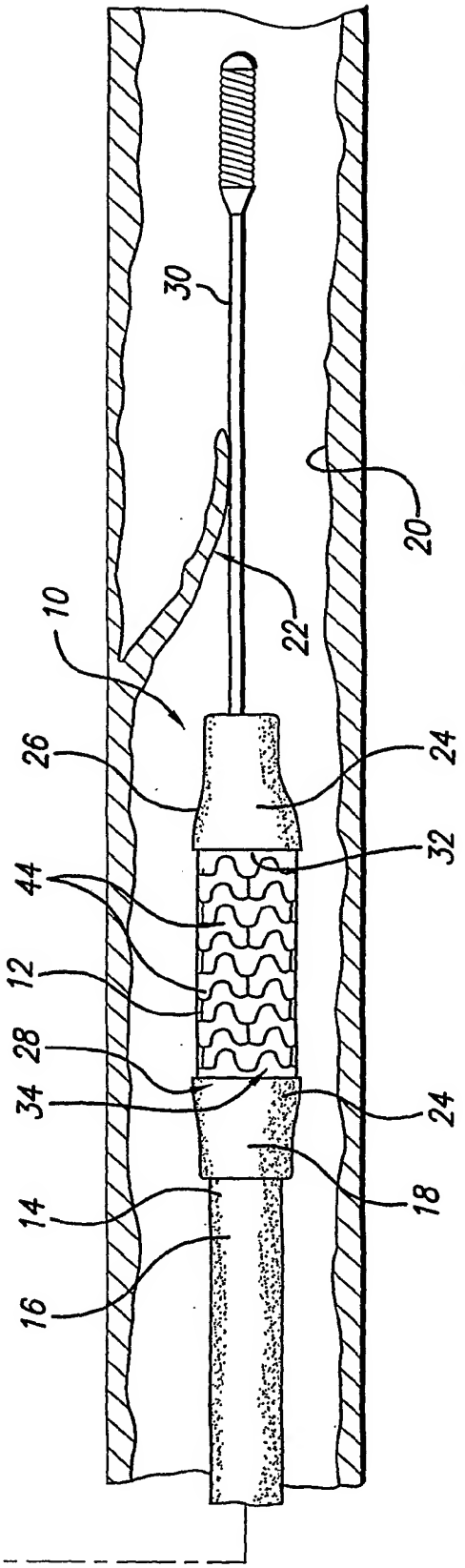

FIG. 2

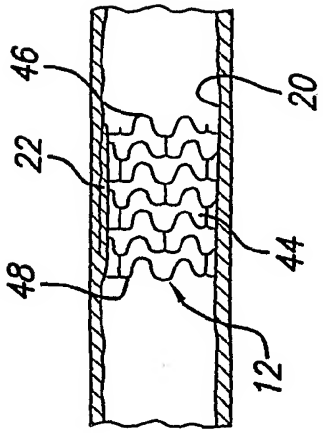

FIG. 3

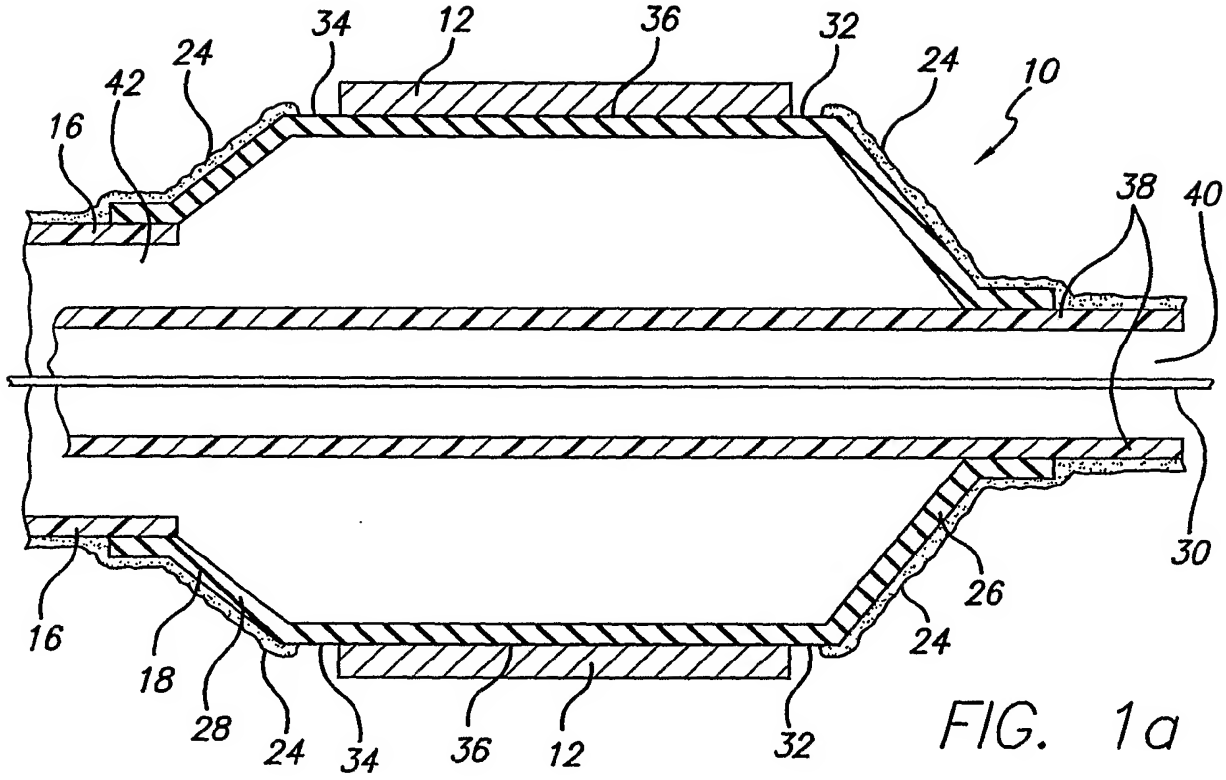
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FIG. 1a

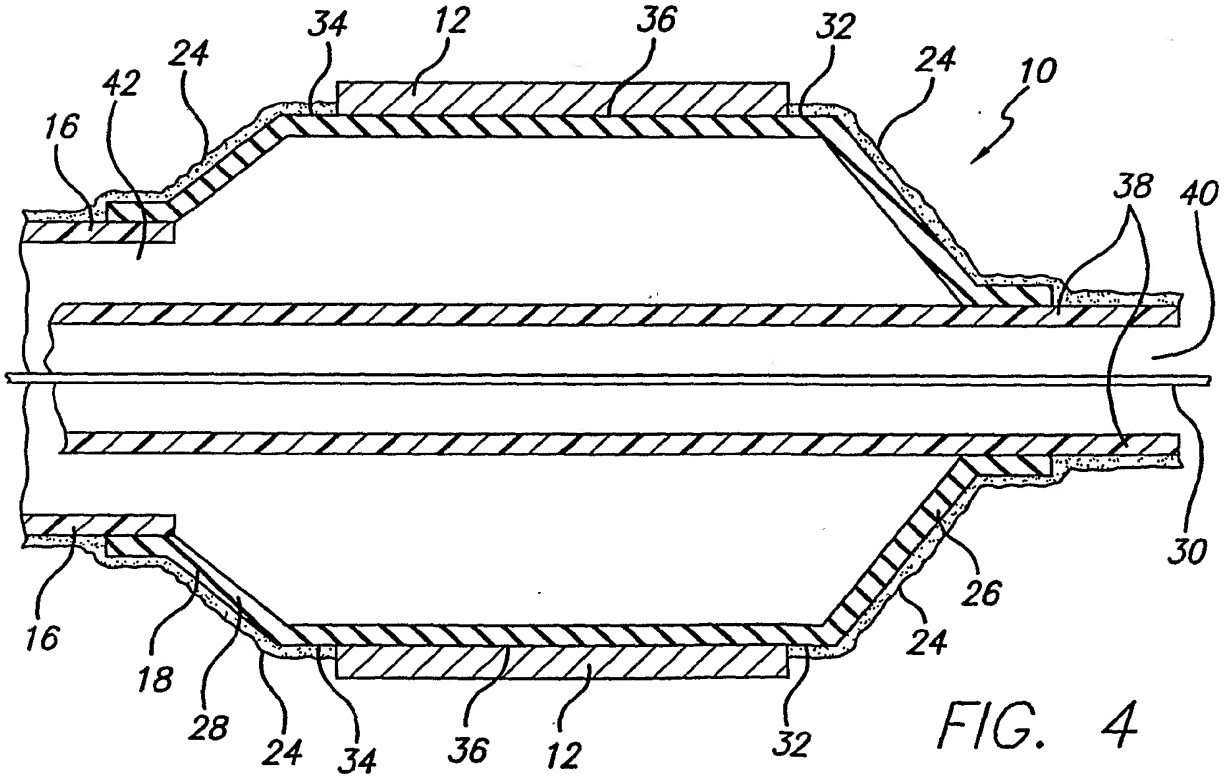
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FIG. 4

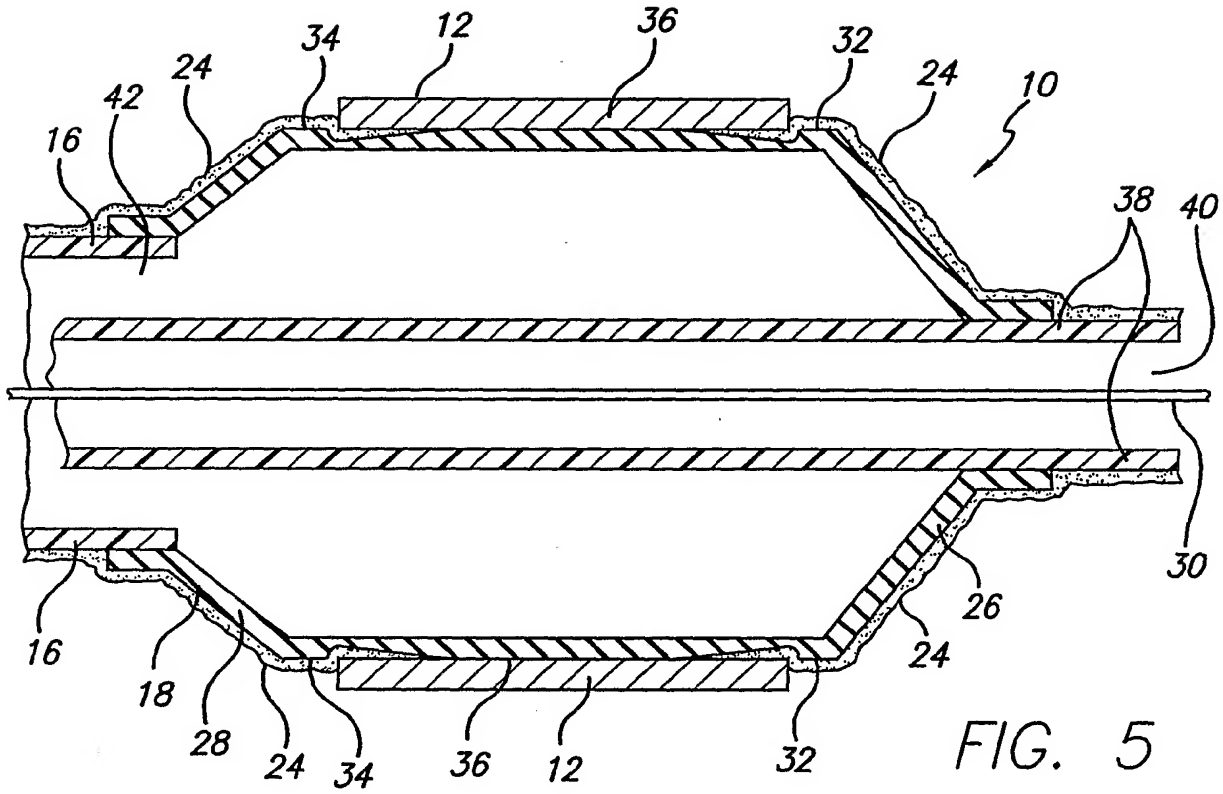
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FIG. 5

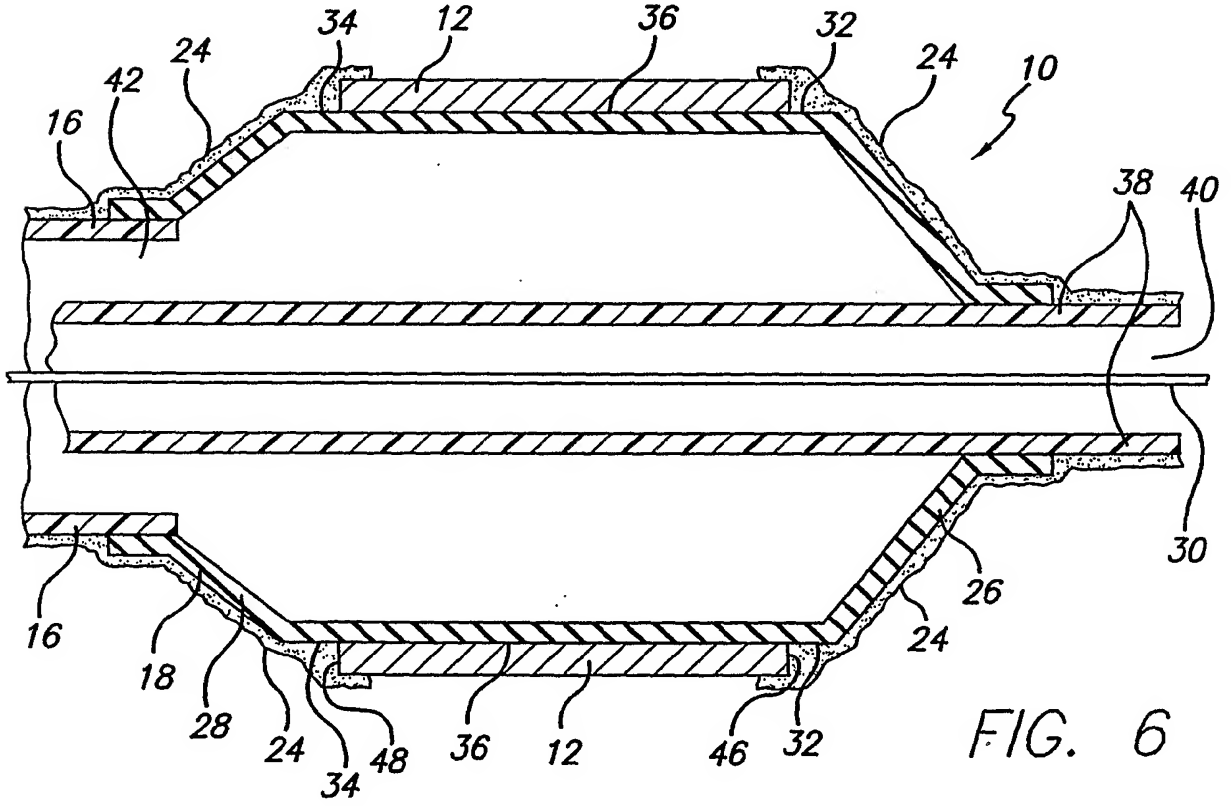
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FIG. 6

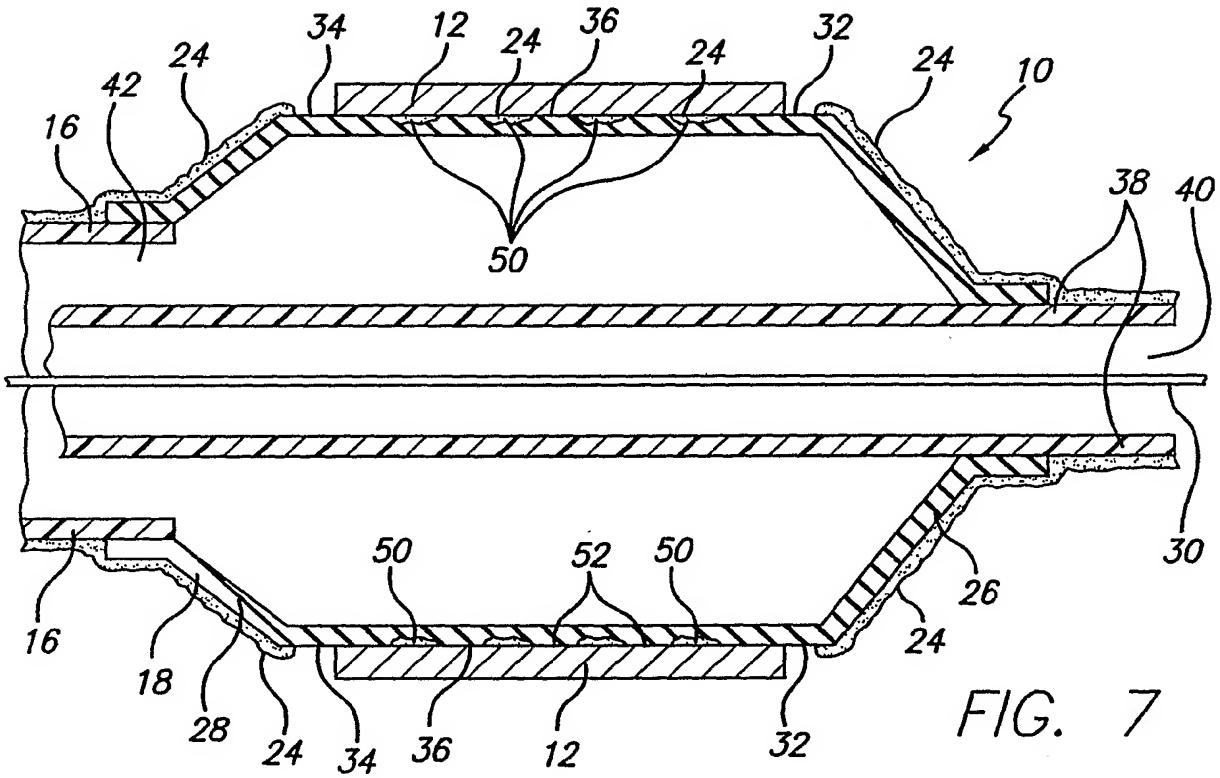
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FIG. 7

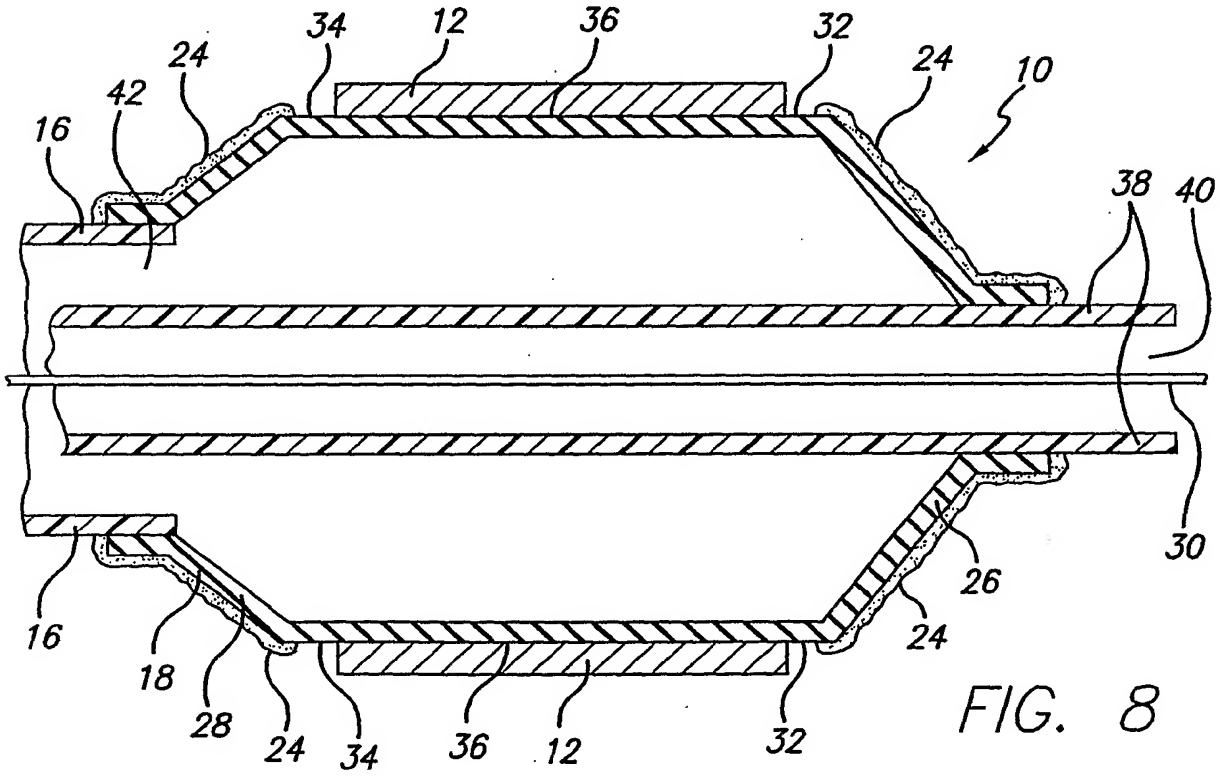
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FIG. 8

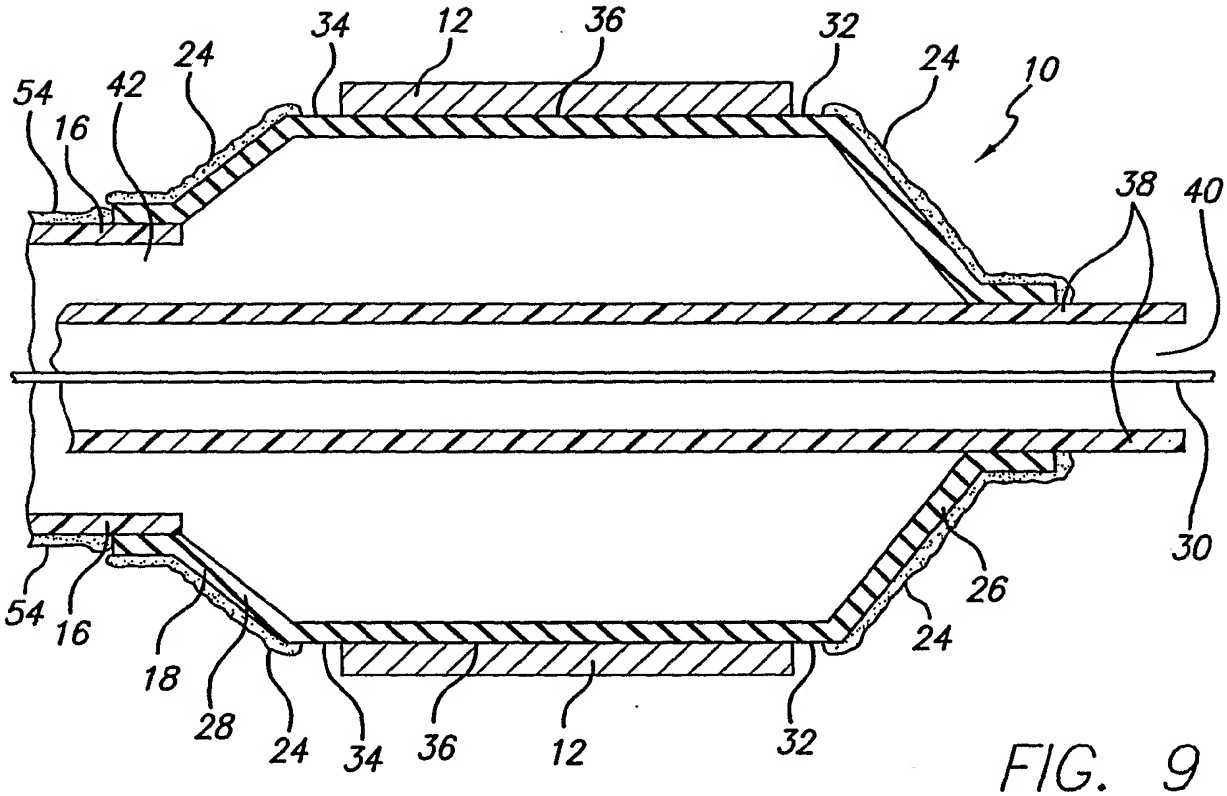

FIG. 9

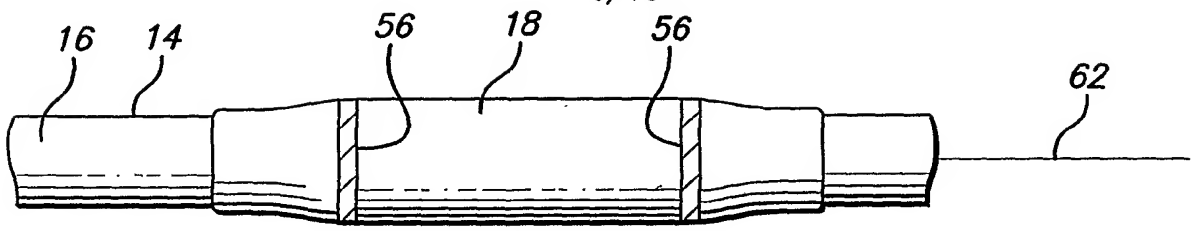

FIG. 10a

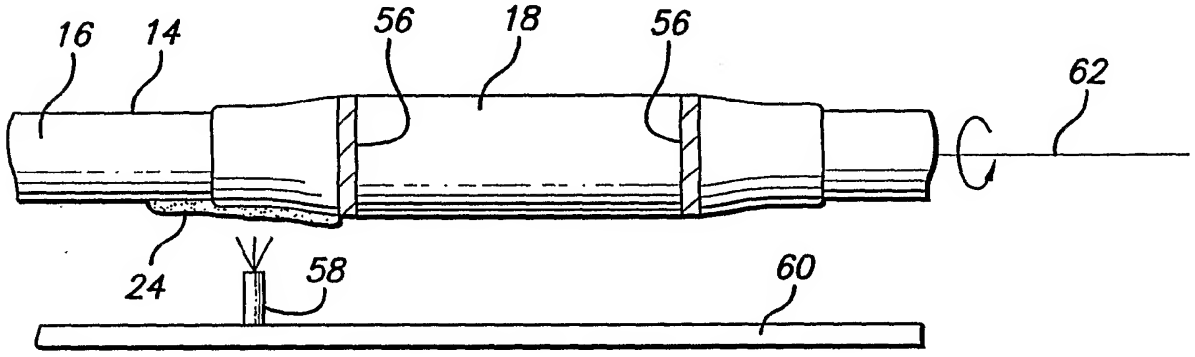

FIG. 10b

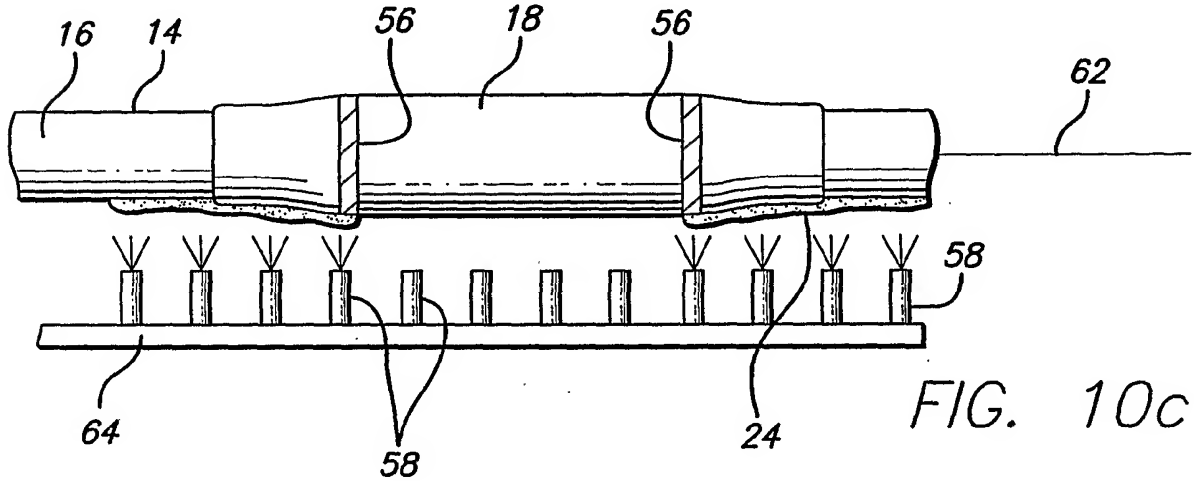

FIG. 10c

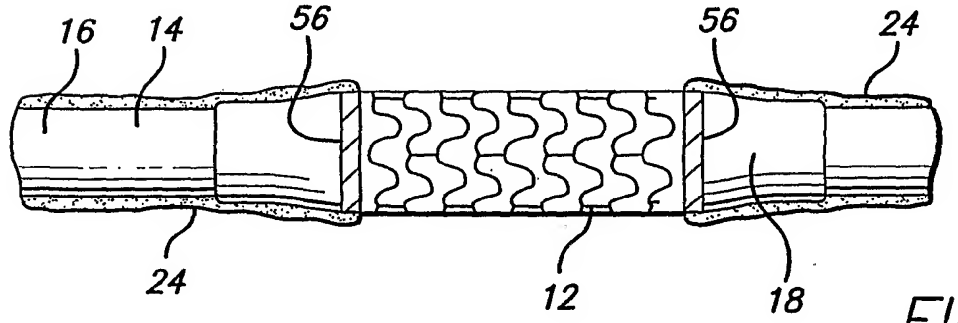

FIG. 10d

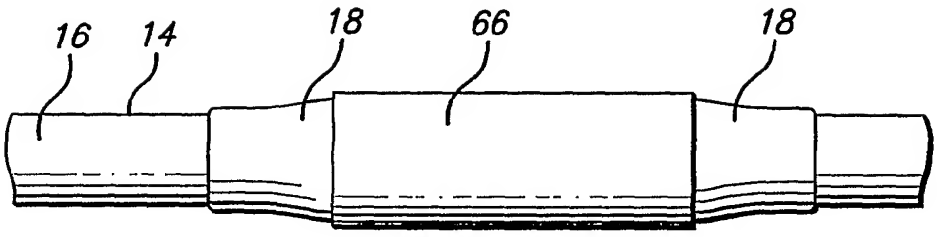

FIG. 11a

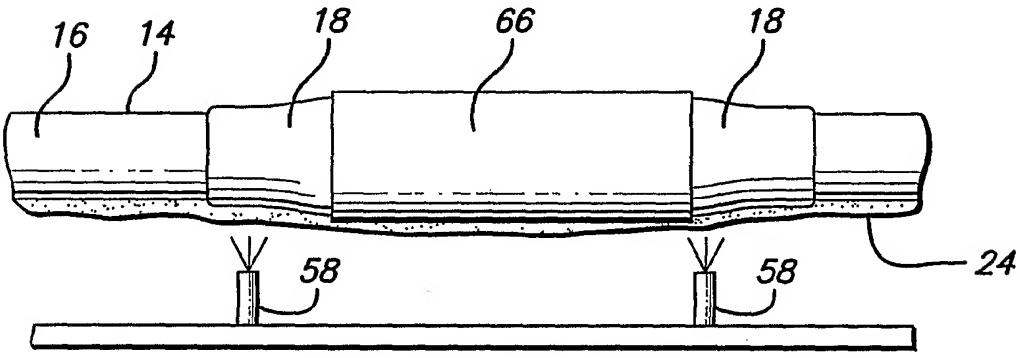

FIG. 11b

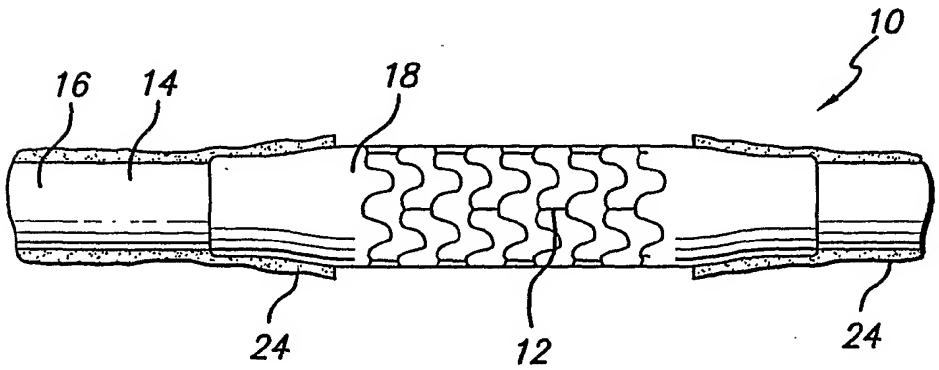

FIG. 11c

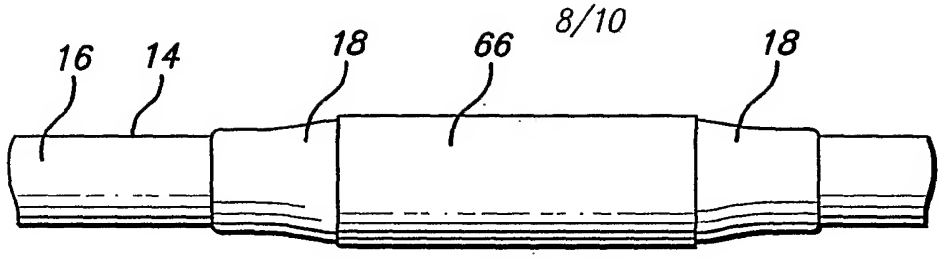

FIG. 12a

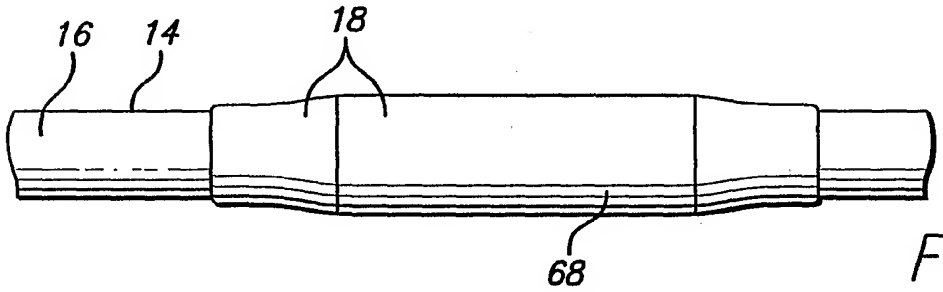

FIG. 12b

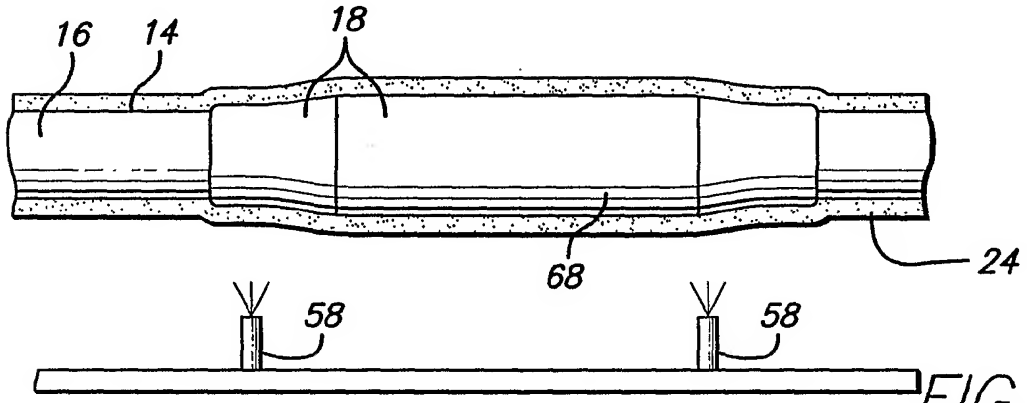

FIG. 12c

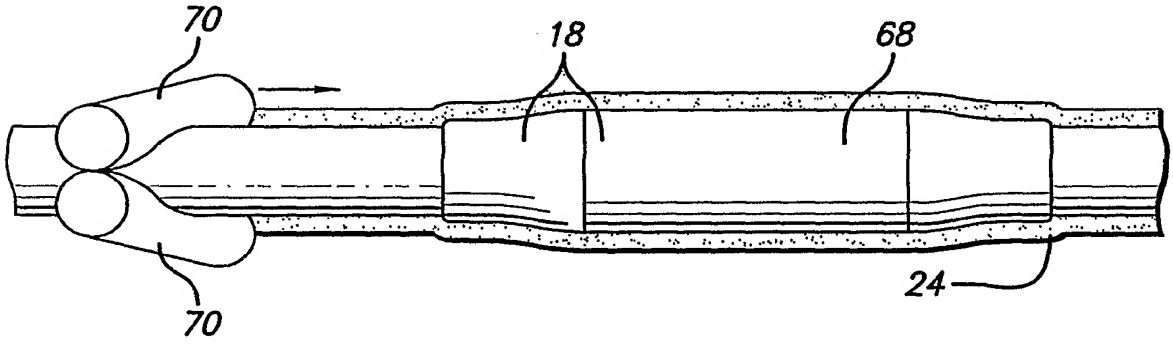

FIG. 12d

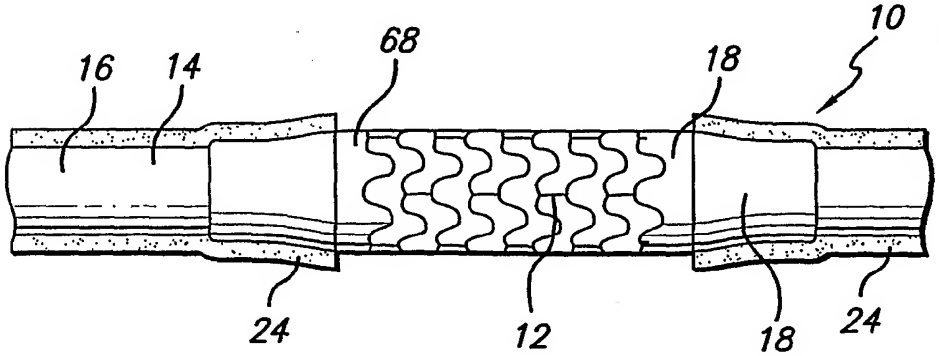

FIG. 12e

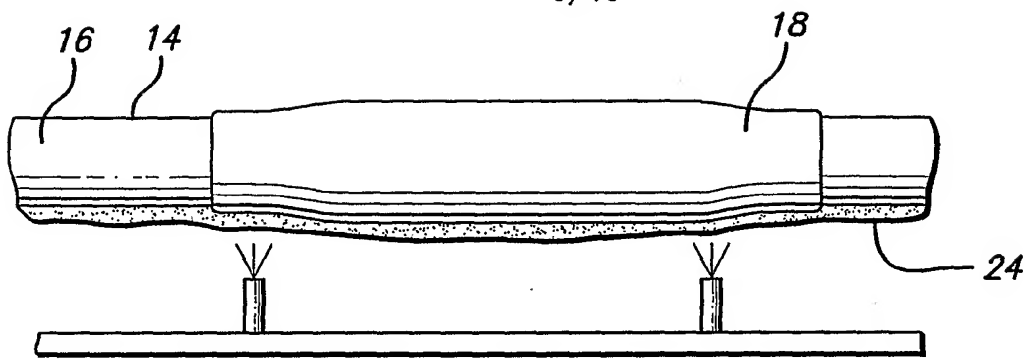

FIG. 13a

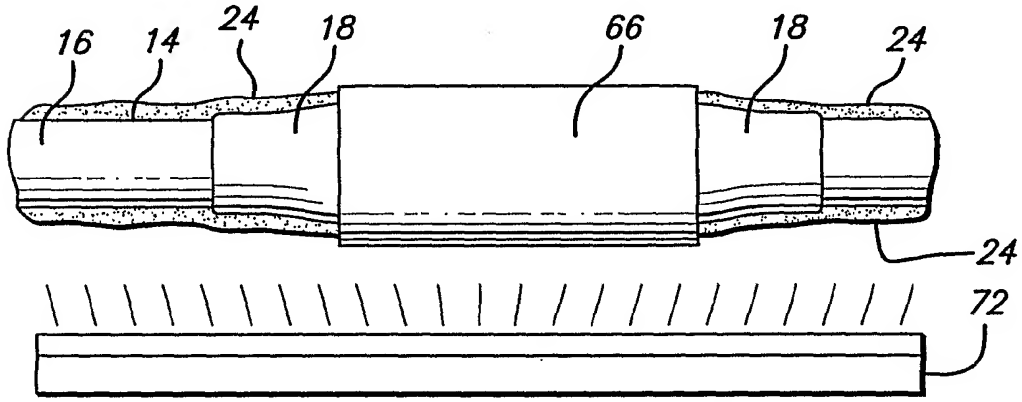

FIG. 13b

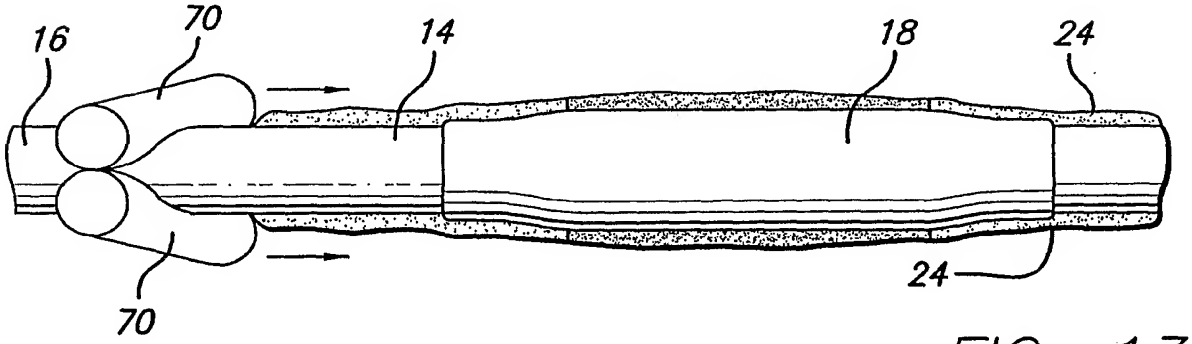

FIG. 13c

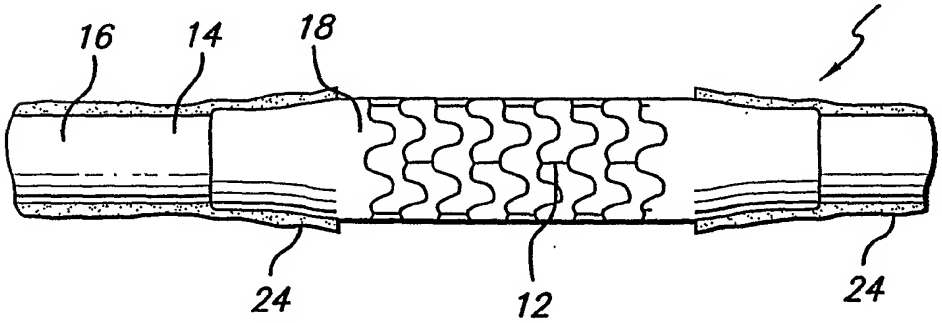

FIG. 13d

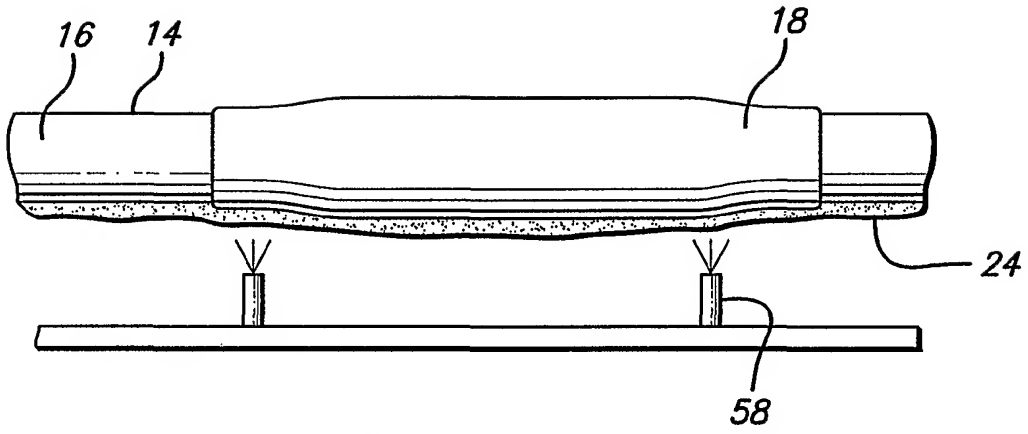

FIG. 14a

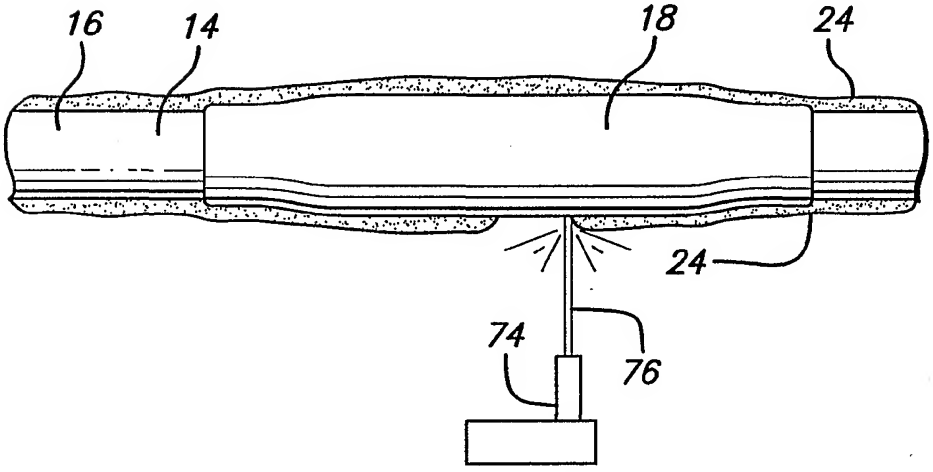

FIG. 14b